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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,118	06/28/2000	R. C. Quijano	VENPROO.007C1	6405

27581 7590 01/27/2004
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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT PAPER NUMBER

3738

27

DATE MAILED: 01/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/605,118	Applicant(s) QUIJANO ET AL.	
	Examiner Brian E Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-36, 39-41, 52-58, 60-69, 73-79, 81-91, 94-100 and 102-117 is/are pending in the application.

4a) Of the above claim(s) 39-41, 53-58, 61, 62, 74-79, 82, 83, 95-100, 103, 104, 116 and 117 is/are withdrawn from consideration.

- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-36, 52, 60, 63-69, 73, 81, 84-91, 94, 102 and 105-115 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2000 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/23/03 has been entered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the **stitches** forming an angle less than 15° or 30° must be shown or the feature(s) canceled from the claim(s). According to Fig. 4 the stitches are parallel to one another or form a straight line, which is definitely not an angle. No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30-36,52,60,63-69,73,81,108-115 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Although the disclosure mentions the use of stitches to form a seam and that there is an angle less than 15° or 30° for the cut on the valved conduits on page 6, there is no support for the **stitches** being formed at an angle less than 15° or 30°.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 30-34,60,84-91,102,105-115 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Quijano et al. (5500014) in view of Richter et al. '734. Quijano et al. disclose valvular prostheses can be formed from a biological graft with a biological valve for defective blood vessels, col. 5, lines 10-15. Quijano also discloses the configuration depends on the intended use of the prosthesis (col. 8, lines 5-6) and also that valved conduits are needed to repair larger vessels, col. 14, lines 51-59. With respect to claims 34,67,88,112 the valves are fully capable of opening at pressures as low as 1mm Hg and remain sealably closed to withstand backflow pressure greater than

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200 mm Hg. Quijano discloses that the tissue is fixed using an aldehyde, col. 10, lines 1-7. Quijano additionally discloses bovine or equine jugular veins can be used, col. 10, lines 12-14. Quijano does disclose the use of sutures for stitching the ends to other tissue, col. 6, lines 43,55-57. However, Quijano does not disclose joining two segments for a bifurcated section of a damaged vessel. Richter et al. teach to join two conduits together at adjacent inflow ends (Fig. 10) forming a vascular prosthetic where the joined end has a cross-sectional area larger than any of the inflow ends of the conduits (Fig. 11) and the outflow ends can be used for a bifurcation. It would have been obvious to one of ordinary skill in the art to use the teaching of joining two conduits together as taught by Richter with the grafts of Quijano by stitching in order to provide a vascular prosthesis for use in blood vessels comprising branched vessels. Thus in view of the combined teachings the inflow end is suitable for attachment to a heart and the outflow ends are suitable for attachment to pulmonary arteries. It can be construed that joining two of the Quijano conduits as shown in Figs. 16A,16C would have an angle less than *about* 30° because the ends are angle cuts.

Regarding claims 35,36,68,69,89,90,113,114 Quijano as modified by Richter do not disclose the cross-sectional area of the inflow end of the graft being greater than 22 or 28mm. It would have been an obvious matter of design choice to have an inflow end with a cross-sectional area greater than 22 or 28 mm, since applicant has not disclosed that this diameter provides any advantage, or is used for any particular purpose, or solves any stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the dimension taught

by Quijano or claims 35,36,68,69,89,90,113,114 dimensions because both ends perform the same function of providing an increased diameter at the inflow end, considering the typical size of an artery.

Claims 52,94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quijano et al. '014 in view of Richter et al. '734 as applied to claim 30 above, and further in view of Ehrenfeld (5156619). Quijano et al. as modified by Richter is explained supra. However, Quijano in view of Richter do not disclose stitching to form a seam is in a single pass for the bifurcated replacement vessel. Ehrenfeld shows (Figs. 3,5) that stitching in the form of single passes are used in attaching tubular conduits together for a graft. Ehrenfeld also teaches that stitching is done such that it is placed on an even continuous suturing surface, col. 3, lines 57-61. It would have been obvious to one of ordinary skill in the art to use single pass stitching as taught by Ehrenfeld as the means to join graft segments of Quijano as taught by Richter in order to provide means of permanent attachment and reduce any chance of detachment of the joined segments.

Claims 63-69,81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quijano et al. '014 in view of Richter et al. '734 and Mobin-Uddin (5078735). Quijano et al. as modified by Richter is explained supra. However, Quijano in view of Richter do not disclose the angled slice less than 15 degrees at an inflow end. Mobin-Uddin show (Figs. 7-9) an angled slice in a graft for joining with another segment and the angle can be construed to be "about" 15 degrees. The use of "about 15 degrees" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited because *about* can mean $\pm 10\%$ or $\pm 0.5\%$. It would

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have been obvious to one of ordinary skill in the art to use the angled slice as taught by Mobin-Uddin to join graft segments of Quijano modified by Richter in order to provide a smaller angled slice for attachment with another angled cut conduit.

Claim 73 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quijano et al. '014 in view of Richter et al. '734 and Mobin-Uddin '735 as applied to claim 63 above, and further in view of Ehrenfeld '619. Quijano et al. as modified by Richter and Mobin-Uddin is explained supra. However, Quijano in view of Richter do not disclose stitching to form a seam is in a single pass for the bifurcated replacement vessel. Ehrenfeld is explained supra. It would have been obvious to one of ordinary skill in the art to use single pass stitching as taught by Ehrenfeld as the means to join graft segments of Quijano as taught by Richter and Mobin-Uddin in order to provide means of permanent attachment and reduce any chance of detachment of the joined segments.

Response to Arguments

Applicant's arguments filed 10/23/03 have been fully considered but they are not persuasive. Note that Quijano does disclose that tissues are sutured, col. 6, lines 43,55-57. Additionally, it is well known that stitching is used to join tissues together in surgical procedures.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-

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5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

TC 3700, AU 3738

A handwritten signature in black ink that reads "Brian E. Pellegrino". The signature is written in a cursive style with a large, stylized 'B' and 'P'.